

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF

BENIGNI ET AL

PATENT NO: 7,241,899

ISSUED: JULY 10th, 2007

FOR: Methods for the Preparation, Isolation and
Purification of Epothilone B, and X-Ray Crystal Structures
of Epothilone B

FILE VIA USPTO EFS-WEB

Mail Stop: Petitions
Director, U.S. Patent & Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

**APPLICATION TO CORRECT PATENT TERM ADJUSTMENT PERIOD
IN GRANTED PATENT UNDER 37 C.F.R. §§ 1.181 & 1.705**

Sir:

The granted patent erroneously lists the patent term adjustment period as 169 days. In fact, the patent term adjustment period should be 310 days, as explained below.

The USPTO ("the Office") made two errors in calculating the patent term adjustment for events that occurred after it mailed the Notice of Allowance. The Office improperly charged Applicants with 120 days of delay for filing a substitute Oath and Declaration and another 49 days of delay for Applicants' late payment of the issue fee.

Applicants Should Be Charged with 28 Days Instead of 120 Days of Delay for Filing the Substitute Oath and Declaration after a Notice of Allowance

The Office charged Applicants with 120 days of delay for filing a substitute Oath and Declaration after a notice of allowance, but the number of days of delay should be 28 days in accordance with 37 CFR 1.704 (c)(10).

37 CFR 1.704 (c)(10) states,

Submission of an amendment under §1.312 or other paper after a notice of allowance has been given or mailed, in which case the period of adjustment set forth in § 1.703 shall be reduced by the lesser of :

- (i) The number of days, if any, beginning on the date the amendment under §1.312 or other paper was filed and ending on the mailing date of the Office action or notice in response to the amendment under §1.312 or such other paper; or
- (ii) Four months.

Applicants filed the substitute Oath and Declaration on September 27, 2007 (copy attached as Appendix A) after a notice of allowance. On October 26, 2006, the Examiner mailed an Office communication approving the substitute Oath and Declaration (see, Paragraph B of the communication, copy attached as Appendix B). According to 37 CFR 1.704 (c)(10)(i), the number of days should begin on September 27, 2007 and end on October 26, 2006, which is 29 days. Therefore, instead of 120 days, the reduction due to Applicants' delay with regard to the filing of a substitute Oath and Declaration should be 29 days.

The Office's calculation of 120 days of delay regarding Applicants' filing of a substitute Oath and Declaration appears to be based on 37 CFR 1.704 (c)(10)(ii), *i.e.*, four months (120 days) after Applicants' filing of a substitute Oath and Declaration. Such a calculation is incorrect for at least two reasons. First, 37 CFR 1.704 (c)(10) clearly states that the number of days to be reduced should be the lesser of 37 CFR 1.704 (c)(10)(i) and 37 CFR 1.704 (c)(10)(ii). In the instant case, the lesser of 37 CFR 1.704 (c)(10)(i), *i.e.*, 29 days, and 37 CFR 1.704 (c)(10)(ii), *i.e.*, 120 days is 29 days.

Furthermore, on October 26, 2006, the Office started the clock for calculating the period of abandonment and revival of the present application under 37 CFR 1.704 (c)(3) due to Applicants' failure to pay issue fee on October 25, 2006. Therefore, the clock for calculating time reduction for Applicants' amendment after a notice of allowance under 37 CFR 1.704 (c)(10) should be stopped on October 25, 2006 rather than October 26, 2006, the date the Office mailed the response to Applicants' substitute Oath and Declaration. For this reason, Applicants submit that the actual number of days to be reduced, starting from September 27, 2007 and ending on October 25, 2006, should be 28 days.

Applicants Should Not Be Charged with 49 Days of Delay for the Late Payment of Issue Fee

The issue fee of this application was due October 25, 2006. Applicants did not pay the issue fee until December 13, 2006. The Office thus charged Applicants with 49 days of delay for the late payment of the issue fee. However, the Office should not have charged Applicants with any delay because the period from October 25, 2006 to December 13, 2006 runs concurrently with the period from October 25, 2006 to April 13, 2007, for which the Office charged Applicants with 170 days of delay for abandonment and revival under 37 CFR 1.704 (c)(3).

As discussed above, on October 26, 2006, the Office started the clock for calculating the period of abandonment and revival under 37 CFR 1.704 (c)(3) due to Applicants' failure to pay the issue fee on October 25, 2006. On April 13, 2007, the Office stopped the clock and charged Applicants with 170 days of delay in accordance with 37 CFR 1.704 (c)(3).

37 CFR 1.704 (c)(3) states that the calculation of time reduction begins on the date after the date the issue fee was due, which was October 26, 2006 in the instant case, and ends on the earlier of: (i) the date of mailing the decision reviving the application, which was May 24, 2007 in the instant case (copy attached as Appendix D); or (ii) the date that is four months after the date the grantable petition to revive the application was filed, which was April 13, 2007 in the instant case (Applicants filed the petition to revive the application on December 13, 2006, copy attached as Appendix C). In the instant case, the earlier of 37 CFR 1.704 (c)(3)(i) and 37 CFR 1.704 (c)(3)(ii) is April 13, 2007. Thus, the Office appeared to be correct in charging Applicants with 170 days of delay starting from October 26, 2006 and ending on April 13, 2007. However, because the Office has already charged Applicants with 170 days of delay from October 26, 2006 to April 13, 2006, the Office should not have charged Applicants with another 49 days of delay running from October 26, 2006 to December 13, 2006.

Calculation of Patent Term

The patent term adjustment history from PAIR shows a USPTO Delay of 517 days and Applicants' Delay of 348 days, calculated as follows:

USPTO Delay:

07-25-2006	Mail Notice of Allowance	429 days
07-10-2007	Patent Issue Date Used in PTA Calculation	<u>88 days</u>
		517 days

Applicants' Delay:

12-13-2006	Issue Fee Payment Verified	49 days
05-24-2007	Petition Granted	170 days
09-27-2006	Substitute Oath and Declaration	120 days
09-25-2006	Information Disclosure Filed	2 days
09-18-2006	Amendment after Notice of Allowance	<u>7 days</u>
		348 days

As explained above, the delay of 120 days for filing a substitute Oath and Declaration on September 27, 2006 and the delay of 49 days for the late payment of the issue fee on December 13, 2006 were erroneously charged to Applicants. Accordingly, Applicants' period of delay should be recalculated to 207 days:

Applicants' Delay:

12-13-2006	Issue Fee Payment Verified	0 days
05-24-2007	Petition Granted	170 days
09-27-2006	Substitute Oath and Declaration	28 days
09-25-2006	Information Disclosure Filed	2 days
09-18-2006	Amendment after Notice of Allowance	<u>7 days</u>
		207 days

Using the corrected period of Applicants' delay, the patent term adjustment should be 310 days: 517 days USPTO delay – 207 days Applicant delay = 310 days patent term adjustment.

As Applicants believe the errors are ascribable to the Office, Applicants request correction of the patent term adjustment to 310 days. The patent is not subject to any terminal disclaimer that would impact such a correction.

Timeliness of this Application

As this application is being filed within two months of the patent's issue date, it is timely under 37 C.F.R. § 1.705(d).

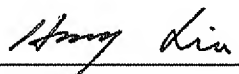
Application Fees

Please charge the fee prescribed in 37 C.F.R. § 1.18(e) to Deposit Account Number 19-3880. If any additional fees are required for consideration of this application, the Office may charge those fees to Deposit Account No. 19-3880 in the name of Bristol-Myers Squibb Company.

Respectfully submitted,

Bristol-Myers Squibb Company
Patent Department
P.O. Box 4000
Princeton, NJ 08543-4000

Date: *Sept. 10, 2007*



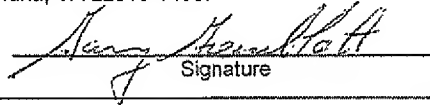
Hong Liu
Attorney for Applicants
Reg. No. 54,891
Phone No. (609) 252-5312

Appendix A – Applicants' Substitute Oath and Declaration

CERTIFICATE OF MAILING

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to the: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Gary D. Greenblatt
Type or print name


Signature

9/25/06
Date

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF

DANIEL BENIGNI, ET. AL..

APPLICATION NO: 10/805,724

FILED: 03/22/2004

FOR: METHODS FOR THE PREPARATION, ISOLATION AND
PURIFICATION OF EPOTHILONE B, AND X-RAY CRYSTAL
STRUCTURES OF EPOTHILONE B

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Substitute Declaration

Sir:

Applicants respectfully submit a Substitute Declaration for the above application. In compliance with 37 CFR 1.63 the newly signed declaration has been signed by all inventors.

The substitute declaration in the present divisional application is being submitted to provide a single declaration to replace the following declarations:

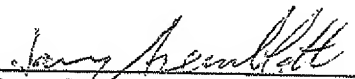
- a) the declaration filed in the parent application 10/668,032, in which nine persons were deleted from the list of inventors and with Daniel Benigni remaining as a common inventor in the parent application and the present divisional application; and
- b) the declaration filed in the present divisional application in which Jack Gougoutas and John DiMarco were added as new inventors.

Applicants believe no fee is due. If this is incorrect, the Commissioner is hereby authorized to charge any additional fees under § 1.17 to Deposit Account No. 19-3880 in the name of Bristol-Myers Squibb Company.

Bristol-Myers Squibb Company
Patent Department
P.O. Box 4000
Princeton, NJ 08543-4000

9/25/06

Respectfully submitted,



Gary Greenblatt
Agent for Applicant
Reg. No. 47,609

Appendix B – Office's Response to Applicants' Substitute Oath and
Declaration Filed on September 27, 2006



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

RP/

LD0283
US-DIV 1

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/805,724	03/22/2004	Daniel Benigni	LD0283 DIV 1	9239
23914	7590	10/26/2006	EXAMINER	
LOUIS J. WILLE BRISTOL-MYERS SQUIBB COMPANY PATENT DEPARTMENT P O BOX 4000 PRINCETON, NJ 08543-4000			LILLING, HERBERT J	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 10/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

RECEIVED
BMS PATENT LAW

OCT 30 2006

Docketed Item PTD Com
Due Date Greenblatt
Attorney Greenblatt



UNITED STATES DEPARTMENT OF COMMERCE

U.S. Patent and Trademark Office

Address: COMMISSIONER FOR PATENTS

P.O. Box 1450

Alexandria, Virginia 22313-1450

APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
---------------------------------	-------------	---	---------------------

EXAMINER

ART UNIT

PAPER

20061024

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner for Patents

Receipt is acknowledged of the papers filed September 18, 2006, September 25, 2006 and September 27, 2006:

A. The prior art filed September 25, 2006 has been entered into the file. The prior art does not anticipate the claimed inventions as well as the prior art does not suggest or motivate one of ordinary skill in the art to prepare a toluene containing epothilone B clathrate which has the advantages as recited:

Crystallization from toluene/ethyl acetate solvent mixtures (e.g., 1:1 mixture) results in preferential incorporation of toluene in the clathrate channels (i.e., obtain form epoB-TO.beta., not epoB-EA.beta.). Both hydrogen-bond donors of the epothilone (hydroxy groups) involved in interepothilone hydrogen bonds and are not available to bind to, and constrain, the guest solvents. The HPLC purity was 99.77 area % (excluding toluene area %). Residual solvents in the cake were 15.3% w/w toluene and 0.3% w/w EtOAc. The mother liquor and wash contained only 0.5% of the epothilone B input activity.

B. The substitute declaration oath filed September 27, 2006 has been approved for the three inventors.

C. The amendments to the claims filed September 18, 2006 have been approved.

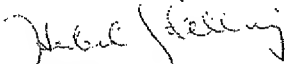
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Lilling whose telephone number is 571-272-0918 and Fax Number is (703) 872-9306 or SPE Jon Weber whose telephone number is 571-272-0925. Examiner can be reached Monday-Friday from about 7:30 A.M. to about 7:00 P.M. Any inquiry of a general nature relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://portal.uspto.gov/external/portal/pair>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

H.J.Lilling: HJL
(571) 272-0918
Art Unit 1657
October 24, 2006

Serial Number 10/805,724

ATTACHMENT: IDS 1449 (2 PAGES)


HERBERT J. LILLING
Primary Examiner
Art Unit: 1657

Appendix C –Applicants’ Petition for Revival of the Application

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

**PETITION FOR REVIVAL OF AN APPLICATION FOR PATENT
ABANDONED UNINTENTIONALLY UNDER 37 CFR 1.137(b)**Docket Number (Optional)
LD0283 DIV 1

First named inventor: Benigni et al

Application No.: 10/805,724

~~XXXXXX~~ Confirmation No. 9239

Filed: March 22, 2004

Examiner Herbert Lilling

Title: Methods for the Preparation, Isolation and Purification of Epothilone B, and X-Ray Crystal Structures of Epothilone B.

Attention: Office of Petitions

Mail Stop Petition

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

FAX (571) 273-8300

NOTE: If information or assistance is needed in completing this form, please contact Petitions Information at (571) 272-3282.

The above-identified application became abandoned for failure to file a timely and proper reply to a notice or action by the United States Patent and Trademark Office. The date of abandonment is the day after the expiration date of the period set for reply in the office notice or action plus an extensions of time actually obtained.

APPLICANT HEREBY PETITIONS FOR REVIVAL OF THIS APPLICATION

NOTE: A grantable petition requires the following items:

- (1) Petition fee;
- (2) Reply and/or issue fee;
- (3) Terminal disclaimer with disclaimer fee - required for all utility and plant applications filed before June 8, 1995; and for all design applications; and
- (4) Statement that the entire delay was unintentional.

1. Petition fee☐ Small entity-fee \$ _____ (37 CFR 1.17(m)). Applicant claims small entity status. See 37 CFR 1.27.☒ Other than small entity - fee \$ 1500 (37 CFR 1.17(m)) Please charge the \$1500 fee to Deposit Account 19-3880 in the name of Bristol-Myers Squibb Company**2. Reply and/or fee**

A. The reply and/or fee to the above-noted Office action in the form of _____ (identify type of reply):

- ☐ has been filed previously on _____.
- ☐ is enclosed herewith.

B. The issue fee and publication fee (if applicable) of \$ _____.

- ☐ has been paid previously on _____.
- ☒ is enclosed herewith.

[Page 1 of 2]

This collection of information is required by 37 CFR 1.137(b). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 1.0 hour to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

3. Terminal disclaimer with disclaimer fee

- ☐ Since this utility/plant application was filed on or after June 8, 1995, no terminal disclaimer is required.
- ☐ A terminal disclaimer (and disclaimer fee (37 CFR 1.20(d)) of \$ _____ for a small entity or \$ _____ for other than a small entity) disclaiming the required period of time is enclosed herewith (see PTO/SB/63).

4. STATEMENT: The entire delay in filing the required reply from the due date for the required reply until the filing of a grantable petition under 37 CFR 1.137(b) was unintentional. [NOTE: The United States Patent and Trademark Office may require additional information if there is a question as to whether either the abandonment or the delay in filing a petition under 37 CFR 1.137(b) was unintentional (MPEP 711.03(c), subsections (III)(C) and (D)).]

WARNING:

Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.

Gary Greenblatt
Signature

12/13/06
Date

Gary Greenblatt
Typed or printed name

47,609
Registration Number, if applicable

Bristol-Myers Squibb Company
Address

609-252-3850
Telephone Number

P.O. Box 4000, Princeton, New Jersey 08543-4000
Address

Enclosures: ☐ Fee Payment

☐ Reply

☐ Terminal Disclaimer Form

☐ Additional sheets containing statements establishing unintentional delay

☒ Other: Issue Fee Payment

CERTIFICATE OF MAILING OR TRANSMISSION [37 CFR 1.8(a)]

I hereby certify that this correspondence is being:

☐ Deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to: Mail Stop Petition, Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450.

☒ Transmitted by facsimile on the date shown below to the United States Patent and Trademark Office at (571) 273-8300.

December 13, 2006

Date

Gary Greenblatt
Signature

Gary Greenblatt
Typed or printed name of person signing certificate

**Appendix D – Office's Grant of Applicants' Petition for Revival of the
Application**



UNITED STATES PATENT AND TRADEMARK OFFICE

LD0283
US-DIV1

COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
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ALEXANDRIA, VA 22313-1450
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OFFICE OF PETITIONS

LOUIS J. WILLE
BRISTOL-MYERS SQUIBB COMPANY
PATENT DEPARTMENT
P O BOX 4000
PRINCETON NJ 08543-4000

In re Application of
Daniel Benigni, et al.
Application No. 10/805,724
Filed: March 22, 2004
Attorney Docket No. LD0283 DIV 1

ON PETITION

This is a decision on the petition under 37 CFR 1.137(b) to revive the above-identified application, filed December 13, 2006.

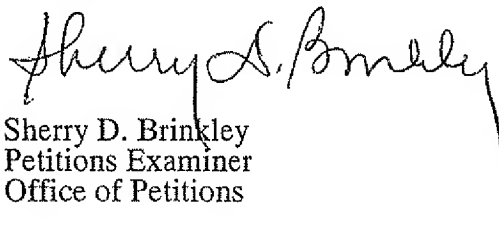
The petition is **GRANTED**.

The application became abandoned for failure to pay the issue fee on or before October 25, 2006. A Notice of Abandonment was mailed on December 11, 2006. On December 13, 2006, the present petition was filed.

The petition satisfies the requirements of 37 CFR 1.137(b) in that petitioner has supplied (1) the reply in the form of the \$1,400 issue fee and the \$300 publication fee; (2) the petition fee of \$1,500; and (3) an adequate statement of unintentional delay.

The application is being referred to the Office of Publications to be processed into a patent.

Telephone inquiries related to this decision should be directed to the undersigned at (571) 272-3204. Telephone inquiries related to processing at Publishing Division should be directed to (571) 272-4200.


Sherry D. Brinkley
Petitions Examiner
Office of Petitions

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MAY 29 2007

Docketed Item PEG
Due Date _____
Attorney LU